K041637

SEP - 1 2004

Section 2

510(k) Summary

1. **Applicant:** Envisioneering, LLC
   1982 Innerbelt Business Center Drive
   St. Louis, MO 63114

2. **Date Prepared:** March 22, 2004

3. **Trade Name:** TargetScan™ Biopsy needle Guide

4. **Common Name:** Biopsy Needle Guide

5. **Establishment Registration Number:** pending

6. **Establishment Address:** Envisioneering, LLC
   1982 Innerbelt Business Center Drive
   St. Louis, MO 63114

7. **Classification Names:** This system is a Class II device.

   Diagnostic Ultrasound Transducer (21 CFR 892.1570; Procode ITX)

8. **Identification of Predicate Device(s):**
   The predicate device for the biopsy needle guide is:
   - Civco Transrectal Needle Guide (K970514)

9. **Device Description:**
   The sterile TargetScan™ Biopsy needle Guide is designed to be used with the Targetscan™ Transrectal Ultrasound system. This needle guide contains a curved needle path which is positioned along the shaft of the probe and is held in place by a biopsy attachment. It allows a flexible biopsy needle to be directed into the tissue at an angle to the probe shaft.

   This needle guide is intended for use with the TargetScan™ transrectal probe Model #TS-360-P which is the subject of a separate submission.

10. **Intended Use**

    Purpose and Function of the Device
    This device is indicated for performing planned and targeted ultrasound guided transrectal biopsies of the prostate when used with the Envisioneering TargetScan Ultrasound/ system.

    Intended Patient Population
    This system is intended to be used with adult patients.

Intended Environment of Use
This system is intended for use by medical professionals in a physician office or hospital environment.

11. Technological Characteristics compared to those of the Predicate Device

Biopsy Guide

The subject and predicate devices are designed for secure and aligned fit to the transducer while not altering transducer design integrity or function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2004

Envisioneering, LLC
% Ms. Chantel Carson
Section Manager
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
NORTHBROOK IL 60062, USA

Re: K041637
Trade/Device Name: TargetScan Biopsy Needle Guide
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: 90 ITX and 78 FCG
Dated: August 19, 2004
Received: August 23, 2004

Dear Ms. Carson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041637

Device Name: TargetScan Biopsy Guide

Indications for Use:

This device is indicated for performing planned and targeted ultrasound guided transrectal biopsies of the prostate when used with the Envisioneering TargetScan model TS-360-P probe.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use

(Per 21 CFR 801.109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041637